

Remarks

Reconsideration is respectfully requested. Claims 1-17 were pending. Claims 1, 7, 8, 11 and 15 are amended. No claims are canceled or added. Therefore, upon entry of this amendment, claims 1-17 will be pending.

Priority Claim

On August 14, 2007, Applicants filed a Preliminary Amendment requesting correction of the priority claim. Specifically, the priority claim was amended to indicate that the present application also "is a continuation-in-part of and claims priority from PCT Application No. PCT/US02/04468, filed February 15, 2002." The initial priority claim noted that the applications claimed priority to the PCT application but did not specify the relationship between the present application and PCT Application No. PCT/US02/04468. To date, Applicants have not received an updated Filing Receipt with the corrected priority claim. Applicants respectfully request entry of the Preliminary Amendment and correction of the priority claim.

35 U.S.C. § 112

Claim 7 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly lacking antecedent basis for the terminology "at least about 0.25 g." Claim 7 has been amended to depend from claim 1. Applicants request withdrawal of the rejection.

35 U.S.C. § 103(a)

Claims 1-9 and 11 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Stone (U.S. Patent No. 6,432,929). Applicants disagree and request reconsideration.

Independent claims 1 and 8 have been amended to recite, in part, a method for making a beverage wherein glucosamine (GLCN) is present in the beverage during heat pasteurization.

Stone discloses a beverage comprising glucosamine wherein a cartilage supplement is added to drink base "preferably but not necessarily, at temperatures below those used in a heat pasteurization process." (Col. 8, ll. 19-21.) Stone also discloses that pasteurization parameters range from a low of about 165 °F for 3 minutes to about 200 °F for less than 40 seconds. (Col. 8, ll. 61-64.) The Office action states, "Since the reference's teaching is not limited to the preferred embodiments, the claimed beverage and a method of making the same are *prima facie* obvious over the teachings by Stone." (Office action, page 3.) This conclusion is incorrect.

Stone does not teach or suggest preparing a drink comprising glucosamine and *subsequently* heat pasteurizing the drink. In fact, Stone teaches away from pasteurizing the drink after addition of the cartilage supplement and states, "[T]he total residence time of the cartilage solution at elevated temperatures is minimal, thereby minimizing any heat inactivation of the cartilage supplement." (Col. 8, ll. 42-45.) Stone further emphasizes this point by stating that the cartilage supplement may be added to the juice base prior to pasteurization when "using pasteurization processes that *do not include heat processing*, such as, but not limited to, filter sterilization or radiation sterilization." (Col. 9, ll. 1-6.)

The preferred method disclosed in Stone comprises preparing a drink base using a pasteurization process at a relatively high temperature in a first step. The pasteurized drink base is then cooled. In a second step, a cartilage supplement-containing solution is prepared at a relatively low temperature. The low-temperature, cartilage supplement-containing solution is then added to the previously pasteurized drink base "at ambient temperatures or as low as 35 °F, for example." (Col. 7, line 59 to col. 8, line 15.) Stone also discloses introducing a cartilage supplement solution "into the liquid stream at a point in transfer lines, preferably at a distance

from the mixing tank, where the temperature of the flowing mixture is lower than the temperature in the mixing tank. This allows the cartilage solution to mix into the product *at temperatures below pasteurization temperature....*" (Col. 8, ll. 32-39, emphasis added.) Thus, although the supplement may be added at elevated temperatures, the implication is that the beverage is being cooled at the time the supplement is added, and the supplement will not remain at pasteurization temperatures for any significant period of time. Upon reading Stone, one of ordinary skill in the art would conclude that heat pasteurizing a beverage after addition of glucosamine would inactivate the glucosamine and eliminate its potential benefits.

For at least the reasons stated above, the methods of claims 1 and 8 are not obvious in view of Stone. Therefore, Applicants request that the 35 U.S.C. § 103(a) rejection of claims 1 and 8 be withdrawn.

Claims 2-7 and 9 depend from claims 1 or 8 and are allowable for the reasons set forth in relation to claims 1 and 8, and further in view of the patentable combinations of features recited in the dependent claims. For example, claim 9 recites that the amount of GLCN in the beverage "after heat-pasteurizing is at least about 80% of the first amount of GLCN in the GLCN beverage prior to heart-pasteurizing." There is no disclosure in Stone regarding a quantity of GLCN remaining after heat pasteurizing a beverage containing GLCN. As previously discussed, Stone does not teach or suggest adding GLCN to a beverage prior to heat pasteurization.

Claims 10 and 12-17 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Stone in view of Yang *et al.* (Chemical Agricultural Society, (1998), 36(6):555-564) and Applicants' alleged admittance on page 10 of the specification. Applicants disagree and request reconsideration.

Stone discloses a pasteurized beverage containing glucosamine, but does not disclose glucosamine derived from fungal biomass and containing levulinic acid or melanoidins. Yang *et al.* disclose a method for acid hydrolysis of certain fungi to produce a solution containing glucosamine. The instant specification discloses methods for producing compositions including levulinic acid and melanoidins, and makes an educated guess that these components might be formed when glucans in the chitin-containing fungal cell walls are converted to dextrose and then hydroxymethylfurfural, which then is converted into melanoidins, formic acid, and levulinic acid. (Page 10, ll. 16-25.) The Office action states that it would have been obvious to prepare Stone's beverage by substituting glucosamine using the method taught by Yang.

Claim 10 depends from claim 1 and recites that the glucosamine is derived from a fungal biomass containing chitin. Claim 10 is not obvious in view of Stone combined with Yang *et al.* As discussed above in relation to claim 1, Stone does not teach or suggest preparing a drink comprising glucosamine and subsequently heat pasteurizing the drink. Stone also does not teach or suggest deriving glucosamine from fungal biomass. Yang *et al.* do not cure the deficiencies of Stone. Yang *et al.* do not teach or suggest preparing a glucosamine-containing beverage and subsequently pasteurizing it. Additionally, although Yang *et al.* disclose an acid hydrolysis of fungal mycelium powder to produce a glucosamine acid solution, there is no indication whatsoever that glucosamine prepared by Yang's method would be suitable for consumption in a beverage. In fact, the Yang product is not suitable for such use.

Yang *et al.* test for fungal contaminants in cereals by treating a small sample of fungal mycelium/cereal powder with very concentrated (10 N) HCl for 16 hours, followed by a second acid treatment using 2N HCl at 121°C for 2 hours, and then performing a colorimetric test on the resulting solution to determine if any glucosamine is present. (Translation pp. 1-4.) The MPEP teaches that prior art can be modified or combined to reject claims as *prima facie* obvious as long

as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). (MPEP § 2143.02). However, no person of ordinary skill in the art would reasonably expect that a method for testing for contaminants in cereals using a highly concentrated HCl for many hours would be useful as a successful method for obtaining commercial amounts of glucosamine suitable for consumption in a beverage product. Thus, claim 10 is non-obvious over Stone in view of Yang *et al.*

Claims 12-17 recite beverage compositions comprising glucosamine along with levulinic acid and/or melanoidins. The Examiner alleges, "[A]pplicant admits on page 10 of the specification that melanoidins and levulinic acid are bi-products of conversion of fungal biomass to glucosamine." (Office action, page 3.) No such admission is made (this point is discussed further below). The Office action then concludes it would have been obvious to prepare a beverage disclosed by Stone by substituting glucosamine prepared using Yang's acid method treatment of fungi, thus producing a beverage containing melanoidins and levulinic acid. This conclusion assumes melanoidins and levulinic acid are inherently present in fungal biomass-derived glucosamine. That assumption is improper.

Applicants do not admit that melanoidins and/or levulinic acid are inherent byproducts of conversion of fungal biomass to glucosamine (as alleged by the Examiner). The present disclosed methods of obtaining glucosamine from chitin-containing fungal biomass involve multiple chemical reactions within a complex chemical system. Applicants hypothesize that melanoidins and/or levulinic acid might be produced during a part of such reactions taking place as glucosamine is obtained by one or more of the disclosed methods. The specification does not, however, state that melanoidins and/or levulinic acid are necessarily or inherently produced when glucosamine is obtained from fungal biomass by any other method. As the Examiner knows, inherency requires that the alleged levulinic acid and melanoidins be necessarily

produced using Yang's method. There is no evidence to support such a theory, especially given the unpredictability of chemical reactions.¹

As is understood by persons having ordinary skill in the art, the products and/or byproducts of a chemical reaction often depend upon the reaction conditions. Yang *et al.* disclose a significantly different method for producing glucosamine as compared to Applicants' disclosed methods. There is no indication that melanoidins and/or levulinic acid are obtained by Yang's described method. Additionally, given the significant differences in the reaction conditions, one cannot assume that melanoidins and/or levulinic acid would be necessarily present in the glucosamine as byproducts of Yang's method.²

Accordingly, because the disclosed glucosamine compositions and Yang's glucosamine composition are not produced by identical or substantially identical methods, and Yang *et al.* do not disclose the presence of melanoidins and/or levulinic acid in their glucosamine composition, no *prima facie* case of obviousness has been established. Thus, neither inherency nor obviousness has been established.

Furthermore, even *if* melanoidins and/or levulinic acid were to form during Yang's process of obtaining glucosamine, it still would not be obvious to use Yang's glucosamine to prepare Stone's beverage. As discussed in relation to claim 10, one of ordinary skill in the art would not reasonably expect success in using a method for detecting contaminants in cereal crops to produce a food-grade product for use in beverages. There is no teaching or suggestion in Yang *et al.* that the disclosed method of obtaining glucosamine for use in a colorimetric assay

¹ "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is *necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999), (emphasis added), MPEP § 2112 IV.

would produce glucosamine that is suitable for human consumption in a beverage. Thus, a person of ordinary skill in the art would find no motivation to combine Yang *et al.* with Stone.


For at least the reasons set forth above, claims 12-17 are non-obvious over the cited prior art, and Applicants request withdrawal of the rejection.

If there are any minor issues to be resolved before a Notice of Allowance is granted, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

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² "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established." *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). (MPEP § 2112.01.)